

U.S. DISTRICT COURT
DISTRICT OF VERMONT
FILED

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

CLERK

BY LAW
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[UNDER SEAL],

Plaintiff,

v.

[UNDER SEAL],

Defendant.

Case No. 2:17-cv-00179-cr

FIRST AMENDED COMPLAINT

FILED IN CAMERA AND UNDER
SEAL

PURSUANT TO 31 U.S.C. §3730(b)(2)

DOCUMENT TO BE KEPT UNDER SEAL
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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT**

**UNITED STATES OF AMERICA, ex rel.
AMANDA B. LONG,**

Plaintiff,

vs.

**MODERNIZING MEDICINE, INC.,
DANIEL CANE, and DR. MICHAEL
SHERLING,**

Defendants.

Case No. 2:17-cv-00179-cr

**FIRST AMENDED COMPLAINT FOR
VIOLATION OF FEDERAL FALSE
CLAIMS ACT**

**FILED IN CAMERA AND UNDER
SEAL
PURSUANT TO 31 U.S.C. §3730(b)(2)**

JURY TRIAL DEMANDED

Plaintiff-Relator Amanda B. Long, through her attorneys, on behalf of the United States of America (the “Government” or the “Federal Government”), for her Complaint against defendants Modernizing Medicine, Inc., Daniel Cane, and Dr. Michael Sherling (collectively, “MMI” or “Defendants”), alleges based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims made and caused to be made by Defendants and/or their agents and employees, in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 et seq. (“the FCA”).

2. This action alleges that MMI caused millions of dollars in false claims to be submitted to the Department of Health and Human Services (HHS). The false claims include federal incentive payments through the Electronic Health Record (EHR) Incentive

Programs and claims for reimbursement for health services billed by MMI's customers to federal health insurance programs including, but not limited to, Medicare, Medicaid, and Tricare.

3. Pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), HHS established the Medicare and Medicaid EHR Incentive Programs (also known as the "Meaningful Use program"), which provided incentive payments through 2017 to healthcare providers who demonstrated "meaningful use" of certified EHR technology.

4. Starting in 2017, the Medicare EHR Incentive program was incorporated into the Merit-based Incentive Payment System (MIPS), one of Medicare's value-based reimbursement programs rewarding cost savings and improved health outcomes. Under MIPS, HHS provides incentive payments to providers using certified health information technology and reductions in reimbursement for providers who do not use certified health information technology.

5. MMI develops and sells EHR software to healthcare providers throughout the United States, including in this judicial district. MMI falsely represented to its certifying bodies and the United States that its software complied with requirements for certification and for the payment of incentives under the Meaningful Use program.

6. To ensure that its product was certified and that its customers received incentive payments, MMI: (a) falsely attested to its certifying body that its software met the certification criteria; (b) obtained certification of its software without ensuring that the software released to customers met certification criteria; (c) caused its users to falsely attest to using a certified EHR technology, when MMI's software could not support the applicable certification criteria in the field; and (d) caused its users to report inaccurate information regarding Meaningful Use

objectives and measures in attestations to the Centers for Medicare & Medicaid Services (CMS).

7. The flaws in MMI's EHR not only rendered the system unreliable and unable to meet Meaningful Use standards, but the flaws also created risks to patient health and safety. Rather than spend the time and resources necessary to correct the flaws in its EHR software, MMI continuously de-prioritized high priority defects in favor of development of new products and new sources of revenue.

8. The most serious problems presented for patient safety involved inaccurate eprescribing of medications where MMI experienced persistent failures of a variety of types. Additional problems included inaccurately charting medical history, date and time of encounter note entries, confusing chart entries between patients, improper prescriptions to children, mix-ups of lab specimens and inaccurate association of lab results with orders.

9. Since 2011, healthcare providers who used MMI's software and attested to satisfying the Meaningful Use objectives and measures received incentive payments through the Meaningful Use program. Had MMI disclosed that its software did not meet the certification criteria, it would not have been certified and its customers would not have been eligible for incentive payments.

10. In addition, flaws in MMI's software caused customers who participated in the Medicare program to submit false and inaccurate reports to CMS under the Physician Quality Reporting System (PQRS), which resulted in the customers receiving higher reimbursement payments from Medicare than they were entitled to receive.

11. MMI also provided remuneration to certain individuals in violation of the Anti-Kickback Statute. Illegal remuneration took various forms including enhanced exclusive interface platform, an e-couponing program, a prescription prior authorization program, a

consulting program, a referral program, a site visit program, and a reference program.

12. Claims to federal health insurance programs for payments, including for federal incentive program payments, that resulted from unlawful kickbacks constitute false claims.

13. Finally, MMI knowingly caused providers using its software to submit to Medicare, Medicaid and other federal payer programs upcoded claims seeking higher level of reimbursement than was medically reasonable and necessary. Upcoded billing was no accident or mere inadvertence. MMI represented to providers that it would increase reimbursement with use of its electronic health record software and it delivered on those representations. The increased billing was the result of knowing decisions in programming its software to boost E/M codes for established patients and adding modifiers to procedure codes without regard to whether the modifier denoting eligibility for additional reimbursement was appropriate.

14. MMI has corrected upcoding for providers who raised concerns that the billing would be caught on an audit by payers but it appears that, even though improper modifiers were removed from certain procedures over the years, improper use of modifiers and increased E/M codes persisted and were ongoing when Relator departed from MMI in 2017.

15. Corporate managers at MMI, including defendants Mr. Cane and Dr. Sherling, directed and participated in the conduct alleged herein and had knowledge of issues with certification, performance, solicitation and payment for referrals in violation of the Anti - Kickback Statute, and inappropriately upcoding billing by providers using its software.

16. MMI's false and fraudulent statements and conduct alleged in this Complaint violate the federal False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.* The FCA allows any person having information about an FCA violation (referred to as a *qui tam* plaintiff or "relator")

to bring an action on behalf of the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

17. *Qui tam* plaintiff Amanda B. Long seeks through this action to recover all available damages, civil penalties, and other relief for the FCA violations alleged herein in every jurisdiction to which Defendants misconduct has extended.

II. PARTIES

18. Plaintiff United States of America is the real party in interest herein. The United States, acting through HHS, administers the Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (Medicare), and administers grants to states for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396, *et seq.* (Medicaid). The United States, acting through HHS, also administers the Meaningful Use program, and the Merit Incentive Payment System (MIPS) and the certification program for EHR technology, now called the “Promoting Interoperability” program.

19. *Qui tam* plaintiff/relator Amanda B. Long (“Relator”) is a resident of Naperville, IL. She is a business executive with substantial experience in product development and product management in the health care field. She worked at MMI from May 5, 2014 until her departure on July 13, 2017. She was initially hired by MMI as Product Director – EMA Enterprise, and after multiple promotions assumed the role of Vice President of Product Management. Relator brings this action on behalf of the United States of America, the real party in interest.

20. Defendant Modernizing Medicine, Inc. is a privately-held Delaware corporation

with headquarters in Boca Raton, Florida. MMI was founded in 2010 by defendants Daniel Cane, Chief Executive Officer and President, and Dr. Michael Sherling, Chief Medical and Strategy Officer. MMI and its affiliated companies manufacture and sell specialty-specific EHR systems. MMI's principal EHR product, called the Electronic Medical Assistant ("EMA"), is a cloud-based system. EMA is presently used in dermatology, gastroenterology, ophthalmology, orthopedics, otolaryngology, pain management, plastic surgery, rheumatology and urology practices. Several Vermont healthcare providers have purchased EMA, including but not limited to Four Seasons Dermatology in Colchester; New England Dermatology in White River Junction; Fletcher Allen Healthcare in Burlington; and Advanced Eyecare Vermont in Bennington.

21. Defendant Daniel Cane is co-founder and Chief Executive Officer and President of MMI. He is a resident of Florida.

22. Defendant Dr. Michael Sherling is co-founder and Chief Medical and Strategy Officer of MMI. He is a practicing Dermatologist and a resident of Florida.

III. JURISDICTION AND VENUE

23. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Although the issue is no longer jurisdictional after the 2009 amendments to the FCA, to Relator's knowledge there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint, as those concepts are used in 31 U.S.C. § 3730(e), as amended by Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02.

24. Moreover, whether or not such a disclosure has occurred, Relator would qualify

as an “original source” of the information on which the allegations or transactions in this Complaint are based. Before filing this action, Relator voluntarily disclosed to the Government the information on which the allegations or transactions in this Complaint are based. Additionally, Relator has direct and independent knowledge about the misconduct alleged herein and that knowledge is independent of and materially adds to any publicly disclosed allegations or transactions relevant to her claims.

25. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found in and/or transact business in the District of Vermont.

26. Venue is proper in the District of Vermont pursuant to 28 U.S.C. §§ 1391(b)-(c) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact business in this District, and because violations of 31 U.S.C. §§ 3729 *et seq.* alleged herein occurred within this District. At all times relevant to this Complaint, Defendants regularly conducted business within this District.

IV. STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act

27. The FCA imposes civil liability on any person who, *inter alia*: (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval; (2) knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government; or (4) conspires

to violate the FCA. 31 U.S.C. §§ 3729(a)(1)(A), (B), (C), and (G).

28. The FCA defines a “claim” to include “any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property that - (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest” *Id.* at § 3729(b)(2).

29. The FCA defines the terms “knowing” and “knowingly” to mean “that a person, with respect to information - (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. *Id.* at § 3729(b)(1)(A). The FCA does not require proof of specific intent to defraud. *Id.* at § 3729(b)(1)(B).

30. The FCA provides that the term “material” means “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” *Id.* at § 3729(b)(4).

31. Any person who violates the FCA is liable for a mandatory civil penalty for each such claim, plus three times the damages sustained by the Government. *Id.* at § 3729(a)(1).

B. The Anti-Kickback Statute

32. The federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), provides, in pertinent part:

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -

(A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) To purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

Shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

33. Accordingly, manufacturers of products paid for in whole or in part by federal healthcare programs may not offer or pay any remuneration, in cash or in kind, directly or indirectly, to induce physicians, medical practices, or others to order or recommend products paid for in whole or in part by Federal healthcare programs such as Medicare and Medicaid.

34. The Patient Protection and Affordable Care Act (PPACA), Publ. L No. 111-48, 124 Stat. 119 (2010), provides that violations of the AKS are per se violations of the FCA: “a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act].”

35. The PPACA also clarified the intent requirement of the Anti-Kickback Statute, and provides that “a person need not have actual knowledge of this section or specific intent to commit a violation” of the AKS in order to be found guilty of a “willful violation.” *Id.*

C. Billing for Reimbursement to Federal Health Care Programs

36. Medicare is a federally-funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted.

37. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, both inpatient and outpatient, if the services are medically necessary and directly and personally provided by the provider. Medicare pays providers only for services that it considers are “reasonable and

necessary for the diagnosis or treatment of illness or injury....” Social Security Act § 1862(a)(1)(A). Providers who wish to participate in the Medicare program must ensure that their services are provided “economically and only when, and to the extent, medically necessary.” 42 U.S.C. 1320c-5(a).

38. Medicaid was also created in 1965 under Title XIX of the Social Security Act. Funding for Medicaid is shared between the Federal Government and those states participating in the program. Thus, under Title XIX of the Social Security Act ("Medicaid"), 42 U.S.C. § 1396 et seq., federal money is distributed to the states, which in turn provide certain medical services to the poor. Federal Medicaid regulations require each state to designate a single state agency responsible for the Medicaid program. The agency must create and implement a "plan for medical assistance" that is consistent with Title XIX and with the regulations of the Secretary of the United States Department of Health and Human Services ("the Secretary"). After the Secretary approves the plan submitted by the State, the state is entitled each quarter to be reimbursed for a percentage of its expenditures made in providing specific types of "medical assistance" under the plan. 42 U.S.C. § 1396b(a)(1). This reimbursement is called "federal financial participation" ("FFP").

39. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. 10 U.S.C. §§ 1971-1104; 32 C.F.R. § 199.4(a).

i. CPT PROCEDURE CODES

40. The Medicare, Medicaid and other federal and state health care programs pay for services rendered to patients by attending physicians and other healthcare professionals in accordance with payment schedules tied to the level of professional effort required to render specific categories of medical care. To ensure normalization of descriptions of medical care rendered and consistent compensation for similar work, both programs tie levels of reimbursement to Current Procedural Terminology (“CPT”) codes that are published and updated annually by the American Medical Association (“AMA”).

41. Base CPT codes are five-digit numbers organized in numeric sequences that identify both the general area of medicine to which a procedure relates (such as “Evaluation and Management,” “Anesthesiology,” “Surgery,” “Radiology,” or general “Medicine”) and the specific medical procedures commonly practiced by physicians and other health care professionals working in that field.

42. Additionally, standard CPT code modifiers are provided by the AMA which make it possible for health care providers to accurately account for increased – or reduced – levels of difficulty and service that may exist with respect to performing standard procedures or providing standard services to specific patients. Medicare carriers use edit screens to prevent payment for codes that should not be paid because they are mutually exclusive, a component of another code, or for a myriad of other reasons. In order to override these edits, a modifier can be attached to the code to explain the unusual circumstance where additional payment is justified.

43. Used properly, CPT code modifiers provide the justification for payment for services that have been altered by some specific circumstance but not changed in definition or code. For example, modifiers may be used to show there are both professional and technical

components to a procedure (to be reimbursed separately). Modifiers may be used to indicate to Medicare that, *inter alia*, on the day a service or procedure was performed a significant, separately identifiable evaluation and management service was also performed (-25 modifier), only the professional component was reported (-26), multiple procedures, other than evaluation and management, were performed on the same day (-51), staged procedure by the same physician during the postoperative period (-58); a procedure or service was distinct from other services performed on the same day (-59), a procedure or service during the postoperative period was unrelated to the original procedure (-79), or surgical assistant services were provided (-80). Used improperly, CPT code modifiers override a carrier's edits and the provider is paid for services for which Medicare intended to deny reimbursement.

44. In 1995, 1997, and again in 2001, the American Medical Association issued Documentation Guidelines for Evaluation and Management (E&M) Services. To determine the appropriate level of E/M services to be coded, seven components must be assessed. These components are history, examination, medical decision making, counseling, coordination of care, the nature of the presenting problem and the time involved in meeting with the patient. The first three (history, examination and medical decision making) are the key components for selecting the level of E/M services. In the case of visits which consist predominantly of counseling or coordination of care, time has been the key or controlling factor to qualify for a particular level of E/M service.¹

45. CMS IOM Pub. 100-04, Medicare Claims Processing Manual, Chapter 12, Section 30.6.1 provides that for "Selection of Level of Evaluation and Management Services,"

¹ 2021 CPT E/M guidelines now provide that the appropriate level of service code be assigned based on the taking of a medically appropriate history and/or examination with the appropriate level of service code based on either medical decision-making or total time based on specific activities codified in the 2021 guidelines.

that “medical necessity of a service if the overarching criterion for payment in addition to the individual requirements of a CPT code. It would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which a specific level of service is billed. Documentation should support the level of service reported. “

D. Certified EHR Technology and the Meaningful Use Program

46. On February 17, 2009, the HITECH Act was enacted to promote the adoption and meaningful use of certified EHR technology. Under the HITECH Act, the HHS Office of the National Coordinator for Health Information Technology (ONC) established a certification program for EHR technology. As part of the certification program, EHR vendors attest to ONC authorized certification bodies (ACB) and accredited testing laboratories (ATL) that their software meets the certification requirements established by ONC. The certification bodies and testing laboratories test and certify that vendors’ EHRs are compliant with the certification requirements.

47. Through the Meaningful Use program CMS makes incentive payments to healthcare providers for demonstrating meaningful use of certified EHR technology. Individual practitioners (Eligible Professionals) could qualify for up to \$43,720 over five years from Medicare (ending after 2016) and up to \$63,750 over six years from Medicaid (ending after 2021).

48. In order to qualify for incentive payments under the Meaningful Use program, Eligible Professionals were required, among other things, to: (1) use an EHR system that qualified as certified EHR technology; and (2) satisfy certain objectives and measures relating to their meaningful use of the certified EHR technology.

49. HHS implemented the certification criteria and incentive payment requirements in multiple stages. On January 13, 2010, HHS published in the Federal Register interim final rules setting forth the “2011 Edition” certification criteria and a proposed rule setting forth the “Stage 1” requirements for incentive payments. HHS finalized these rulemakings by publication in the Federal Register on July 28, 2010. In Stage 1, an Eligible Professional’s use of certified EHR technology generally needed to satisfy fifteen “core objectives” and five out of ten “menu set objectives.”

50. On September 4, 2012, HHS published in the Federal Register the final rules setting forth the “2014 Edition” certification criteria and “Stage 2” requirements for incentive payments. In Stage 2, an Eligible Professional’s use of certified EHR technology generally needed to satisfy seventeen “core objectives” and three out of six “menu set objectives.”

51. On October 16, 2015, CMS published in the Federal Register a final rule with comment period setting forth the “Modified Stage 2” requirements for incentive payments. For years 2015 through 2017, Modified Stage 2 eliminated the concept of “menu set objectives” and required all Eligible Professionals to attest to a single set of objectives and measures.

52. In October 2015, CMS also released a final rule that established Stage 3 in 2017 and beyond, which focuses on using certified EHR technology to improve quality, safety and efficacy of health care, including promoting patient access to self-management tools and improving population health.

53. Starting in 2015, all providers were required to use technology certified to the 2014 Edition. For 2016 and 2017, providers can choose to use technology certified to the 2014 Edition or the 2015 Edition.

54. To qualify for incentive payments in each Stage of the Meaningful Use program, healthcare providers are required each year to attest that they used certified EHR technology and satisfied the applicable Meaningful Use objectives and measures. Use of certified EHR technology and satisfaction of applicable Meaningful Use objectives and measures are material to payment under the Meaningful Use program.

55. To obtain certification, EHR vendors must attest to an ACB that their EHR product satisfies the applicable certification criteria, submit to certification testing by an ATL, and pass such testing.

56. Certification testing is based on the certification criteria the vendor represents its software satisfies and on which it requests to be tested and certified. The certification and testing bodies use standardized testing protocols (“test scripts”), which identify each step the vendor will be required to take during testing. The test scripts are available to vendors in advance of their testing date. These scripts are intended to test representative aspects of the criteria under examination and are not intended to test all aspects of the criteria. The certification body relies on the accuracy and good faith of the vendor’s attestations to the certification body with regard to aspects of the criteria that are not directly tested.

57. After obtaining certification, an EHR vendor must maintain that certification by complying with all applicable conditions and requirements of the certification program. Among other things, the EHR product must be able to accurately, reliably, and safely perform its certified capabilities while in use in doctors’ offices. EHR vendors must cooperate with the processes established by ONC for testing, certifying, and conducting ongoing surveillance and review of certified EHR technology.

58. The CMS rules governing the Meaningful Use program recognize that

healthcare providers rely on certification for assurance that an EHR product meets the applicable certification criteria, including that it possesses the certified capabilities that healthcare providers will need to use to achieve relevant objectives and measures, and that the software will perform in accordance with applicable certified capabilities.

59. Starting in 2017, the Medicare EHR Incentive Program was incorporated into the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program created by the Medicare Access and CHIP Reauthorization Act (MACRA), 42 U.S.C. 1395ee. MIPS is discussed further in ¶¶ 50-53 below.

E. Certified EHR Technology and the PQRS Program

60. The Physician Quality Reporting System (PQRS) is a voluntary reporting program that provides a financial incentive for health care professionals who participate in Medicare to submit data to CMS on specified quality measures for covered Physician Fee Schedule services furnished to Medicare Part B Fee-for-Service beneficiaries.

61. For reporting years 2012 through 2014, CMS provided physicians who satisfactorily reported data on the required quality measures an incentive payment of 0.5% of their total allowed charges for the reporting year. Starting in 2015, the program applied a negative payment adjustment to practices with Eligible Professionals that do *not* satisfactorily report data on quality measures. The penalty was 1.5% for 2015 and increased to 2.0% for 2016 and subsequent years. Those who report satisfactorily for the 2016 program year avoid the 2018 PQRS negative payment adjustment.

62. Providers can participate in PQRS either with or without an EHR. Those who have an EHR can report PQRS data directly through their EHR.

63. The measures for PQRS are divided into two groups: Individual Measures and

Measures Groups. An eligible professional may choose to report any combination of Individual Measures or choose a specific Measures Group. Measures Groups include a minimum of 6 individual measures and normally a maximum of 11 measures. The individual measures in the Measures Groups all relate to a specific diagnosis or problem such as diabetes, coronary heart disease, or others. Also, beginning in 2016, Eligible Professionals must include one cross-cutting measure.

64. The last program year for PQRS was 2016. Starting in the 2017 program year, PQRS became part of the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program. See ¶¶ 50-53 below.

F. The Merit-based Incentive Payment System (“MIPS”)

65. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created the Quality Payment Program to replace three programs that ended with the 2016 reporting period: the Medicare EHR Incentive Program; the PQRS program; and the Value-Based Modifier program.

66. The Quality Payment Program has two tracks: the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models (APMs).

67. MIPS payment adjustments are applied to Medicare Part B payments two years after the performance year, with 2019 being the payment adjustment year for the 2017 performance year.

68. Relator alleges that the practices described herein have caused false claims to be submitted to federal health programs including Medicare, Medicaid, Tricare, and the Medicare Meaningful Use program and the MIPS program.

V. ALLEGATIONS

A. Background: The Corporate Culture of MMI

69. MMI was founded in 2010 by defendants Daniel Cane and Dr. Michael Sherling. Daniel Cane is a successful entrepreneur, whose first major business success was Blackboard.com (an educational tool), which he co-founded while studying at Cornell. Blackboard.com was ultimately taken public and then subsequently sold to private investors for over one billion dollars.

70. Together with co-founder Dr. Sherling, Cain developed MMI like many other hi-tech start-ups, with an emphasis on recruiting smart people, surrounding them with office perks and parties, placing an emphasis on company culture, and raising capital. MMI has raised several hundred million dollars since being founded.

71. While working for MMI for over three years, Relator witnessed how the company's quest for a material valuation skewed decision making. Rather than prioritizing making needed safety and stability improvements to its core healthcare software, MMI focused instead on developing new add-ons and new sources of revenue, with the ultimate goal of exiting the company with a valuation at or exceeding a billion dollars.

72. From Relator's experience in product management, MMI's quest for a higher valuation came at an unreasonable cost by crossing the line on prohibitions against kickbacks and upcoding in federal health programs and ignoring known patient safety through short cuts in software programming.

73. Despite raising millions of dollars, MMI has not fixed certain crucial core deficiencies in EMA. As explained more fully below, critical bugs persisted for years and remained unsolved as of the time of Relator's departure in 2017.

74. MMI also quietly sells patient data (de-identified) to pharmaceutical companies.

It does so as a secondary revenue stream while charging its current client base for basic tasks on top of its premium subscription fees. For example, in addition to the premium subscription charge for the EHR, MMI charges clients for access to audit logs over 30 days old, for many basic reports or extracts of a client's data, and for exports of or access to their data when they are leaving MMI for another EHR.

75. MMI's orientation and corporate culture are reflected in following representative emails by MMI managers.

76. In an internal email on July 1, 2014, several months after EMA received 2014 Edition certification, Jason Ethridge, who was then MMI's Senior Release Manager, expressed his frustration with MMI's inability to provide an EHR that meets MU certification criteria:

Team,
... We continue to fail as a company to actually deliver the MU certified product to "spec" because we divide off a couple individuals and hope they will finish. We continually find new things for our teams to do other than what they have committed to . . . , the teams are hurting, this is terrible for what we are trying to accomplish as a whole. . . We must find a way to understand and own the work in front of us no matter what it is or we will continue to struggle as a whole.

77. In an internal email on December 10, 2014, nearly eight months after EMA received 2014 Edition certification, Adam Gresh, then MMI's Director of Software Engineering, discussed the fundamental inadequacy of EMA's core software code:

There is a continuing decline in the ability to build new features on top of stale code. As we layer on things we discover what went wrong. When we don't fix those things we put hack upon hack upon hack. Thing [sic., Think] of it like Jenga. As you pull pieces from the stack and put the[m] on top it gets harder and harder to make a move. If you don't fix the holes in the tower eventually the whole thing falls over.

It's been 3 years since the last major refactoring of the application. We have, at times, made some incremental improvements. If we want to continue to have good through[put] for features and have bugs that are easy to fix we need to continue to invest in fixing the infrastructure of the APIs where it makes sense. If we don't we spend all our time trying to fix things that got unintentionally broken or build on top of things that are already unstable making them even more unstable.

Imagine that you find out that the tire pressure in the tires is too low because the valve stems are leaking, you forgot to gap the spark plugs, your timing is off and you've got a leaky gas tank because you bottomed the car out pulling into the gas station to put air in the leaky tires. Your problems are getting worse and you're spending more time trying to maintain problems of your own making caused by not maintaining the car correctly.

78. The fundamental problems identified by the Senior Release Manager and the Director of Software Engineering are reflected as well in customer statements of extreme dissatisfaction. In an email on November 20, 2015, MMI's Senior Compliance Specialist summed up the experience of the client base:

[W]hat it really comes down to is the client is upset that we have made no effort until they threaten to do anything about bugs. That we ignore issues and concerns when we claim to hear them. *I hear this everyday from multiple clients.* [Emphasis added.]

B. MMI Failed to Satisfy the Certification Criteria and Made False Statements in Obtaining Certification and Marketing its Software

44. MMI's EHR, EMA, is sold as a complete EHR and a mobile EHR, referred to as EMA and EMA Mobile, respectively. The complete EHR and mobile EHR are based on the same software system; the only difference is that the former is supported on a browser and the latter on an iPad or Android device. The Mobile version is also sold as a smart phone app, called Pocket EMA. In this Complaint, the term "EMA" refers to both the complete EHR and the mobile EHR, unless otherwise noted.

79. On April 16, 2014, EMA version 3.0.0.12 achieved ONC HIT 2014 Edition certification. Two days later, on April 18, 2016, EMA version 4.0 achieved ONC HIT 2014 certification. These two versions functioned as the core EHR products of MMI, to which MMI added periodic upgrades (e.g., version 4.1, 4.2, 4.3 etc.) over time.

80. As a predicate to obtaining certification for these core versions of EMA, MMI submitted Attestation forms to ICSA Labs, an Office of the National Coordinator-Authorized

Certification Body (ONC-ACB), representing that MMI's EHR software satisfied the 2014 Edition certification criteria and that the software was capable of performing those criteria and standards in the field.

81. In addition, MMI's software was tested by an authorized testing laboratory as part of the certification process. According to the respective certification documents, ICSA Labs, the ACB, delegated testing to two accredited testing laboratories: SLI Global Solutions and Drummond Corporation. SLI was the ATL in charge of certification testing for most of the testing of EMA; however, on occasion, Drummond was the ATL.

82. Based upon MMI's attestations, and several days of testing in early 2014 performed by the ATLs, EMA version 3.0.0.12 and EMA version 4.0 achieved 2014 Edition certification on April 16 and April 18, 2014, respectively. These certifications designated that MMI's EHR software is capable of supporting eligible providers with meeting the Stage 1 and Stage 2 Meaningful Use measures required to qualify for funding under the American Recovery and Reinvestment Act (ARRA).

83. As explained more fully below, Relator alleges that:

(a) MMI could -- and did -- pass 2014 Edition certification testing for versions 3.0.0.12 and 4.0 without fully implementing the technological requirements for 2014 Edition certification. MMI was aware that the standards, implementation specifications, and criteria were not met.

(b) MMI's version 3.0.0.12 and 4.0 software, as well as later iterations of each version, did not satisfy the Meaningful Use certification criteria and could not operate in the field in compliance with the requisite certification criteria.

(c) MMI failed to adequately resolve its bugs or service tickets to analyze whether or not software issues impacted the software's ability to meet the standards, implementation specifications, and certification criteria and perform in a reliable manner consistent with its certification.

C. MMI Falsely Attested to Compliance With Certification Requirements And Re-Labeled and Hardcoded its Software to Pass Certification Testing

84. Since the start of the Meaningful Use program, eligibility for incentive payments required Eligible Professionals to use certified EHR technology. An EHR product cannot be certified unless all applicable certification criteria and standards have been met. Certification is material to payment under the Meaningful Use program.

85. Certification testing does not confirm that each criteria and standard is satisfied in full and under every conceivable scenario. Rather, testing takes a snapshot of a product's capabilities by ensuring it can pass certain pre-disclosed test cases.

86. During the course of Relator's employment with MMI, she discovered that the company had engaged in a fraudulent scheme both to obtain certification of its EHR products, and to pass audits required to maintain certification. Relator discovered this information in the following circumstances.

87. In September 2014, Relator was promoted to Senior Director of Product Management at MMI. Her direct reports at the time included the Director of Government Compliance, who will be referred to herein as "DGC." DGC started as an educator within MMI and had been promoted to Director of Government Compliance after the 2011 edition EHR certification. Among other responsibilities, DGC was MMI's lead representative for 2014 Edition certification in early 2014. She is listed as the MMI representative on ICSA Labs' certification documentation for EMA version 3.0.0.12 (certification granted April 16, 2014), and

EMA version 4.0 (certification granted April 18, 2014), as well as later iterations of version 4.0.

88. As Senior Director of Product Management, Relator held regular one-on-one meetings with her team members, including DGC. Relator's first meeting with DGC was on or about September 29, 2014, and she held regular one on one meetings with her thereafter. In these meetings Relator and DGC discussed a range of topics, including problem areas, team management, certification status, and readiness for the next round of certifications, among other issues.

89. Relator was aware at that time that there were many bugs and problems plaguing EMA since she received and had access to reports of the problems with EMA in her position with the company. Relator was concerned that EMA was not functioning at the level required by the MU certification criteria, and she discussed this concern with DGC.

90. Relator asked DGC about DGC's experience with MMI's previous certifications and what was to be expected for upcoming certifications. DGC explained to Relator that she had been moved into the Compliance Department after the 2011 Edition certification, after she began escalating to management evidence that EMA was not working like the certification rules stated that it should. She escalated this information to defendants Daniel Cane (CEO) and Dr. Michael Sherling (CMO), as they had led the first certification back in 2011.

91. DGC explained to Relator that as MMI's lead representative for the 2014 Edition certification testing she had first-hand knowledge of how MMI passed the 2014 certification tests, and that MMI had passed the tests dishonestly. DGC shared the following details with Relator.

92. MMI was not prepared for its 2014 Edition certification testing; consequently, when MMI was offered the choice between onsite testing or remote testing (via computer

conference and screen share), MMI chose the latter option because MMI knew that it would not pass if the testers were onsite. With the knowledge and participation of senior management, MMI devised several deceptive schemes to pass the 2014 Edition certification test. According to DGC, these schemes included:

- MMI downloaded a future version of its EHR product and changed the label of that version so that it appeared to be the version being tested and used the mislabeled version during testing.
- During testing, DGC had multiple tabs open on her computer (which was the one being tested) with different instances of EMA open on each tab, and she switched back and forth between tabs without the certifying body knowing so that she could complete certain test script workflows.
- During testing, the testing body followed the test scripts that MMI knew in advance. Rather than programming the software comprehensively to retrieve the required information in any scenario, MMI had developers hardcode the test script information directly into the server, all for the purpose of making the testing body believe MMI had implemented the required functionality when in fact it had not.
- DGC was instructed by MMI employees in the background (out of view of the testers but in the same room as DGC) to pause the computer screen during the remote testing, and to request breaks, so that MMI employees in the background could manually change what was displayed on the screen so that it appeared to perform the required functions, when it did not in fact have the capacity to perform the functions.

93. Based on the test results, the authorized testing body found that MMI's version 3.0.0.12 and 4.0 met the certification requirements. Based on the findings of the testing body, ICSA Labs certified MMI's version 3.0.0.12 on April 16, 2014 and certified version 4.0 on April 18, 2014.

94. After the testing was concluded, DGC requested access to the server that was used during the testing, but Jason Ethridge, then Senior Release Manager, informed her that it had been destroyed.

95. MMI used similar methods of deception and dishonesty to pass the post-certification surveillance testing conducted by the certifying body in 2014 and 2015.

96. The first post-certification surveillance test was in late 2014 and DGC was MMI's lead representative for the test. MMI knew in advance that its certification body would re-test it using the same or similar testing protocol as in the original certification test, and MMI handled the test in the same dishonest manner as it handled the original certification test. DGC explained to Relator that during the surveillance test, MMI changed the label name again on a future version to make it look like the software version being tested and used other similar schemes to those described above. As a result, despite still failing to meet the certification criteria, MMI passed this surveillance test.

97. In December 23, 2014 DGC was moved out of the position of Director of Government Compliance and into the role of Senior Compliance Specialist. MMI replaced DGC with a new hire, referred to herein as "SPM," who took over DGC's responsibilities and also took on the role of Senior Product Manager of Compliance. SPM was assigned to be the company's lead representative for the next round of Meaningful Use surveillance testing, which was scheduled to take place in January 2015.

98. SPM informed Relator that under pressure from senior managers, she followed the same or similar schemes as those described above to pass the 2015 surveillance testing. For example, on January 15, 2015, SPM wrote an email expressing her discomfort with the practice of falsely relabeling the software:

The audit is on load 4.3. So have to use 4.5 and change the version on the certification box to 4.3!!! To me, this does not sound right but if this is what we have been doing before, then we should not change in few days.

99. DGC expressed the belief to Relator that MMI still, to this day, would be unable to pass a full certification test if the testers were present onsite and MMI was not allowed to use the ruses described above.

100. DGC also expressed the belief that these or similar ruses were used by the company to pass the original 2011 Edition certification in 2011 since many of the same people were involved in the 2011 certification, and the software had even less functionality at that point in time.

101. Internally, MMI employees were open about the company's lack of preparedness leading into 2014 Edition certification. For example, in one internal discussion on the company's "wiki" – internal discussion platform – in a section entitled "The compromises," the author discussed some of the shortcuts planned for upcoming 2014 Edition certification testing, including the following:

. . . . Because the [certification] test data is small, we can make some implementation shortcuts that wont work as well once we're going against more massive production data. For instance in certification pass, we can just synchronously [i.e., occurring at the same time] loop through all patients for the provider and check the logic for each patient record. Post certification, we'll need to make this process more asynchronous

. . . . For cert[i]fication/import we will probably only be looking at data stored in the problem list and procedure log, not equivalent data from within virtual exam. That means that in production, this functionality wont work until finalization populates this

data from data within the virtual exam (which may require some additional SNOMED mappings that dont exist currently.)

. . . . Until we resolve the above issues we'll need to selectively control ability of this functionality to be just for testing/certification boxes not live clients. (not sure what functionality already exists to support that selective release)

. . . . CPT codes are currently computed, but that is very expensive operation. Ideally finalization should store these codes, but for now with certification we will just use the override code to specify the cpt code. Post cert we'll need to add storage on finalization and check both computed and override.

102. The above email is just one representative example illustrating MMI's gaming of the 2014 Edition certification test. The fact that MMI fraudulently obtained certification is also evidenced by numerous bugs and problems in the software in operation that rendered the software non-compliant with the requisite certification criteria. Examples of EMA's failure to meet certification criteria are provided below.

D. MMI's EHR Failed To Satisfy Required Certification Criteria

103. During the period relevant to this complaint, MMI released software without adequate testing and overly relied on customers to identify bugs and other problems. Some bugs and problems -- even some identified as "critical" -- persisted on MMI's bug list for months and even years.

104. Representative examples of the deficiencies in EMA related to Meaningful Use criteria are provided below.

1. MMI's Software Failed to Satisfy Audit Log Requirements

105. In order to be certified to the 2011 and 2014 Edition certification criteria, EHR software must reliably and accurately record user actions in an audit log. Audit logs track user activity in an EHR and provide a chronology of a patient's care.

106. MMI represented to its certification body that it satisfied this audit log requirement. However, MMI's audit logs did not accurately record user actions, and in

certain cases, the audit logs misled users as to events that were conducted during a patient's treatment.

107. Problems with audit logs have been persistent since product launch and continue to the present time. Jonathan Smith, Senior Software Engineer, informed Relator as recently as July 7, 2017 that an estimated five percent of MMI's audit logs are assigned to the wrong patient. He explained that this happens most frequently when EMA has multiple potential matches for a patient (for example, patients with same name). In these instances, the EHR software randomly assigns one of the possible matches to that audit log entry without verifying that it is the correct patient and without generating an error or confirmation message in the system. Mr. Smith informed Relator that he escalated this issue to Rich Kroll, Director of Engineering, but it had not been resolved as of the time of Relator's departure from MMI.

108. MMI has consistently struggled to maintain a functional audit log. Development tickets within MMI (called JIRA Tickets) show a steady influx of complaints about incorrect audit log reports (e.g., assigning incorrect dates/times to the logs and assigning incorrect activities to the logs), data missing from the audit log, non-understandable audit reports, and inability to make more than 30 days of the audit log visible to end users without intervention from MMI (and a charge to the customer), to mention a few.

109. The complaints regarding audit logs were significant enough that on April 24, 2017, certifying body ICSA Labs sent an email to MMI entitled "Complaints received about your certified products," in which ICSA shared the following complaint:

Modernizing medicine! Does not allow users to understand what is tracked in the audit log. They will not provide answers to what we see in the audit log. How do we know if information is not compromised or someone in the office is not accessing data when they should not be?

MMI internally discussed and acknowledged that EMA was not providing a fully functional, understandable audit log, but despite having this knowledge for years, MMI has not prioritized development resources to fix the problem.

2. MMI's Software Has Mixed Up Patient Records

110. Relator is aware of several reported instances in which MMI's EHR mixed up patient records, i.e. placed one patient's information in another patient's record. This is a serious patient safety issue when it occurs. It also undermines the integrity and reliability of the entire EHR system and renders it non-compliant with most certification criteria.

111. Examples of development tickets in which patient records were mixed up are JIRA (Development) Ticket No. 72429, opened 11/16/15, closed 12/17/15 ("Currently there exists a set of patients with links within their charts to other patient's charts. This creates a breach in HIPAA so it is important to fix it in a timely manner."); and JIRA Ticket No. 72287, opened 11/16/15, closed 12/17/15 ("Prescription that was ordered and sent for [Patient A] on November 9th, 2015 has [Patient B] listed on Rx. . . . this is a critical bug.")

112. After release of EMA version 5.5 in June 2017, MMI experienced a major problem involving the mixing up of patient records, and this problem was still not resolved by the time Relator left the company in July 2017. In that incident, a number of EMA users reported that patient data was showing up in the wrong patient's chart. For example:

Ticket No. EMA-99056, created 6/16/17, version 5.5.0.2: "Client is reporting that a visit note from one patient was viewable in two other patient's charts"

113. MMI assigned a Senior Compliance Specialist to lead the task force in 2017 to troubleshoot this issue in Version 5.5. The Senior Compliance Specialist informed Relator that over 4,000 patients and 200 practices were impacted by the problem, including 20 patients who

had potential access to another patient's records via the patient portal.

114. Relator is aware of one incident where a biopsy was taken of a patient and because of the records being mixed, the practice was uncertain of which patient to notify to let them know the results of the biopsy. Also, hundreds of prescriptions were written during this period for which there was a distinct risk of patient harm due to the possibility of the wrong patient receiving the prescription or an inappropriate prescription being prescribed due to inaccurate medical record data. In addition, the problem caused HIPAA violations because of the unauthorized disclosure of confidential patient information to other patients on the patient portal.

115. Relator is informed and believes that MMI was not transparent about the problem with the practices affected, as evidenced by the growing list of escalations from the client base asking for more details about what happened. Even internally, CEO Cane misrepresented the extent of the problem to his employees, telling them during a company-wide meeting that the problem was "not a breach" and that it had been completely resolved, when this was not the case.

116. As of the date of Relator's departure from MMI in July 2017, providers were actively calling and frustrated because MMI would not give them a clear answer as to what was happening, and, according to Jonathan Smith (Senior Software Engineer) and Rich Kroll (Director of Engineering), MMI had not identified the root cause. MMI did not roll back the release, and instead hid visit notes from the patient portal for a three-day window to prevent patients from reading other patients medical records by mistake. This stopgap measure did not work as MMI had more reports of patient records mixed up (one of which included cancer) on July 13, 2017.

117. On July 11, 2017, almost a month after the issue was reported by customers, MMI

sent an “Update” to clients saying that “we have resolved an issue that was discovered after our recent release of EMA version 5.5.0,” referring to the above problem; however, this was misleading as the problem was not fully resolved.

118. Clients did not respond well to the vague explanation, and MMI created a spreadsheet called “Needed Escalations” that detailed some of the responses they were receiving from clients. Relator reviewed the Needed Escalations spreadsheet and noted that several accused MMI of not comprehensively identifying the issue and not being fully transparent with the clients.

119. Relator is informed and believes that the problem of mixing up patient records is a recurrent problem for EMA and was not solved by the time Relator left MMI in July 2017.

3. MMI Failed to Satisfy SNOMED Requirements

120. To be certified as a Complete EHR under the 2014 Edition certification criteria, an EHR must use the Systematized Nomenclature of Medicine - Clinical Terminology (SNOMED) for various purposes, including specifying the medical conditions for diagnosis and problem lists when transmitting a patient’s chart. Using SNOMED enables providers and electronic medical records to communicate in a common language, thus increasing the quality of patient care across many different provider specialties.

121. Relator is informed and believes that MMI selectively mapped SNOMED codes in its software to pass the certification tests but did not have full functionality for SNOMED codes in key locations within the software including the “Virtual Exam Room.”

122. Although MMI originally certified EMA version 3.0.0.12 and 4.0 in April 2014, it did not have required SNOMED vocabulary mapped to key locations within the software including the “Virtual Exam Room” where providers document patient encounter, diagnosis and

treatment plans. This is evidenced by JIRA (development) tickets post certification regarding the absence of SNOMED codes. For example:

- Ticket No. EMA-5762, created 6/3/14, still marked as open as of July 2017, version 4.0.0.1: “SNOMED Mappings from Problem List (specialty history and specialty surgical history) need to be implemented for Plastics [Plastic Surgery practices].”
- Ticket No. EMA-5759, created 6/3/14, marked as resolved on 7/28/14, version 4.0.0.1: “SNOMED Mappings from Problem List (specialty history and specialty surgical history) not working for any specialty other than Derm [Dermatology].”

123. CEO Dan Cane directed employees to use ad hoc methods of mapping SNOMED codes to diagnoses, rather than implementing complete and dynamic mappings. For example, in an email thread to Relator entitled “‘Missing’ SNOMED codes based on icd9 lookups,” dated January 9, 2015, Cane attached an Excel spreadsheet listing over 9,000 MMI diagnosis codes that were not mapped to ICD-9 or SNOMED codes, and Cane suggested the following solution for the missing SNOMED codes: “Fastest way to fix this is to have Danielle simply march through the results and fill in the missing codes.” In other words, rather than programming into the software the capability to appropriately look up and retrieve any SNOMED code from the entire database of SNOMED codes, Cane suggested that an employee should manually fill in the missing SNOMED codes in a discretionary fashion.

124. Another example of MMI’s inability to reliably retrieve SNOMED codes is documented in an internal discussion on MMI’s wiki page. The discussion thread is entitled “ICD9 to SNOMED for Acne.” The problem discussed in the thread was that the ICD-9 code for acne maps to 66 different SNOMED codes. Rather than presenting the user with the decision of which code to select as the most appropriate one for the patient’s particular acne condition, MMI’s EHR selected the first SNOMED code that the system found, not necessarily the most appropriate one. Following is an excerpt of the internal discussion of this flawed software logic:

As an example of the one-to-many mapping of ICD9 to SNOMED codes, the Acne ICD9 code we use is 706.1, and that maps to 66 SNOMED codes. In CDA we are using SNOMED codes for diagnoses, and we have no way to know the “best” code to pick in this case, so we will just pick the first we find. It would be better for our diagnoses to be tagged with a SNOMED in our configuration files and Dr. Sherling has said that we are in the process of doing that.

125. Another problem was that even when EMA did map diagnosis codes to SNOMED, the tables had been loaded so that it was difficult to keep up to date. Internal MMI communications indicate that MMI did not regularly update its SNOMED to ICD9 mapping; instead MMI used ICD-9 codes from 2013 for several years after they were out of date.

4. MMI Failed to Satisfy LOINC Requirements

126. To be certified as a complete EHR under the 2014 Edition certification criteria, an EHR must use the Logical Observation Identifiers Names and Codes (LOINC), the required database and universal standard for identifying medical laboratory tests, measurements, and observations. The LOINC code is captured during the lab ordering process, within the lab system, and in clinical summary documents that are shared between providers.

127. The LOINC code represents a detailed explanation of what laboratory tests were ordered or completed for the patient. Additionally, any result of that lab test that is a numerical value must be recorded as structured data within the EHR.

128. As of 2017, MMI was using an outdated (2014) version of LOINC. Moreover, even the outdated version it did use was not properly mapped to laboratory tests, such that EMA’s system of ordering laboratory tests did not work reliably or accurately. This is reflected in development tickets, two of which are quoted below for illustration:

EMA-78758, opened 4/15/16, closed 6/6/17: “We need to update to the latest version of the LOINC database. We haven’t updated the DB since 2014.”

EMA-75624, opened 2/22/16, closed 6/9/17: “The current model for how labs are ordered in EMA (through use of LOINC) has reached a breaking point. We

simply cannot map the LOINC results back to order codes on a 1:1 basis since, at it's most simple explanation, a LOINC result code can map to a multitude of order codes - it can never be guaranteed that the orderer is actually ordering the right test to generate their result. There are also several more complicated reasons for which the existing system not only doesn't scale, but simply doesn't work."

129. In an internal email on August 24, 2016, Senior Software Engineer Jonathan Smith reported on his investigation of various coding problems, and shared with his colleagues this finding: "The only thing I did was find that Yihzong [MMI software engineer contractor] had incorrectly imported the loinc database."

5. MMI Failed to Satisfy RxNorm Requirements

130. Eligibility for Meaningful Use Stage 2 incentive payments required healthcare providers to use certified EHR technology to, among other things, generate and transmit prescriptions electronically (commonly referred to as ePrescriptions or eRx) using the capabilities and standards specified at 45 CFR 170.314(b)(3), which requires the use of RxNorm. RxNorm is a standardized drug vocabulary that specifies each unique drug, formulation, and dosage. RxNorm codes provide a mechanism for ensuring the accuracy of ePrescriptions and for allowing EHR systems to communicate and interact accurately and efficiently with other EHR systems, with pharmacies, and with health information networks.

131. In an email on May 8, 2014, Luis Moss, MMI Lead Integration Engineer, sent an internal email suggesting that, to pass certification, MMI hardcoded into its test software only those RxNorm codes needed for certification:

Hi All,
I spoke with George today to get a refresher as to why allergies does not always show up in a CCD. It is due to RxNorm. The larger answer is that the certification only required that we pass by setting our test patients with medication allergies. The implementation guide and I think the NIST testing tool required that the allergies have an RxNorm.

This means that allergies in our system that do not have an RxNorm will not show

in the CCD. We can improve this by still inserting an allergy into CCD even if it does not have an RxNorm. We would have to use a NullFlavor value for the RxNorm code and include our id. George mentioned that there is another nationally recognized id that we could use if we had it in our database. I don't think this change is in JIRA.

132. Based on the above email as well as DGC's and SPM's explanation of how the company passed certification and post-certification audits, Relator alleges that MMI hardcoded into its testing software only the RxNorm codes that it knew in advance would be tested by the ATL, rather than programming the capability to retrieve any RxNorm code from the entire database of RxNorm codes, as required by the certification criteria.

133. This conclusion is supported by development tickets in early January 2015. According to these development tickets, in preparation for an upcoming surveillance audit of version 4.0.0.5, scheduled for January 19, 2015, it was discovered during pre-audit testing that RxNorm codes were missing from the CCDA, the Consolidated Clinical Document Architecture required for the summary care document. *See, e.g.*, EMA-13440, created 1/12/15 ("RxNorm not showing on readable ccda for . . . medications and allergies"); EMA-13442, created 1/12/15 ("RxNorms missing for Medication and allergy sections on Readable CCDA"). The solution, according to an entry on January 14, 2015 in development ticket no. EMA-13443, was: "Entered required medications and allergies for audit." This suggests that MMI hardcoded into its test software only those RxNorm codes needed to pass the audit. This conclusion is reinforced by an internal wiki page entitled "RxNorm Data Source" that explains how MMI updates data sources for RxNorm. Under the space for "RxNorm – EMA Release Date," it is empty, which implies that there was no release of EMA with full RxNorm functionality.

134. Lack of full RXNorm functionality can affect capability to eprescribe and the completeness and accuracy of medication lists and the CCDA, among other issues.

6. MMI Failed to Satisfy CQM Requirements

135. Clinical quality measures, or CQMs, are measurements that track the quality of health care services provided by Eligible Professionals. Since 2014, all Medicare-eligible providers beyond their first year of demonstrating meaningful use are required to electronically report their CQM data to CMS using certified EHR technology to be able to receive an EHR incentive payment.

136. Providers scheduled to demonstrate Stage 1 or Stage 2 are required to report on 9 of the 64 approved CQMs. Additionally, all providers must select CQMs from at least three of the six key healthcare policy domains recommended by the Department of Health and Human Services' National Quality Strategy. (The six domains are: Patient and Family Engagement; Patient Safety; Care Coordination; Population and Public Health; Efficient Use of Healthcare Resources; and Clinical Processes/Effectiveness.)

137. Miscalculating CQMs was a persistent problem for EMA. To pass certification testing, MMI took shortcuts and made "compromises" to cover up flaws in the software. In one internal discussion on the company's internal "wiki" discussion platform, in a wiki page entitled "CQM Design and Implementation Notes," under a section entitled "The compromises," an MMI employee discussed shortcuts that MMI planned to make to pass certification testing of the CQM requirement: "Because the [certification] test data is small, we can make some implementation shortcuts that wont work as well once we're going against more massive production data. . . . That means that in production, this functionality wont work . . . Until we resolve the above issues we'll need to selectively control ability of this functionality to be just for testing/certification boxes not live clients. . . ."

138. Having used "shortcuts" and "compromises" to pass certification for the CQM

criteria, MMI experienced many problems post-certification with CQMs not calculating properly. As CMO Dr. Michael Sherling noted in an internal email on July 1, 2014 (three months after certification):

CQMs are not working properly. We can't expect Jonathan to fix them all within this 2 week timeframe.

I need JAVA resources from both of your teams on call to help fix bugs this week. Please synch daily with Karuna and Carrie and keep me posted on the progress. This is now the highest priority.

139. The CQM problem was so serious that in an internal email on the same day, July 1, 2014, Jason Ethridge, then Senior Release Manager, informed a number of employees that fixing the CQM problem was the highest priority: "Team . . . Just to be clear we are going to blow up all sprints and do NO other work until this is done, we will pick up the pieces after."

140. EMA was still not calculating CQMs reliably two years later, as reflected by many customer complaints and development tickets on this subject. As an example, on February 23, 2016, a member of the Compliance team emailed her colleagues:

Here is the list of the priorities for Complaints [sic., Compliance] team. There are many moving targets I would like to make sure management is aware of them.

Frist priority: CQM error: Queued for processing. EMA-75173

- It is needed for MU submission. MU has been extended to March 11. We need this fix as soon as possible. . . .

141. Bugs and problems regarding the calculation of CQMs persisted on MMI's bug list for months and even years after certification.

7. Date/Time Stamp Problems

142. A recurring problem for MMI's EHR was that it assigned incorrect times or dates to office visits and appointments. This flaw creates a patient safety risk because the date and time a medication is administered, or a treatment performed are important pieces of medical

information for a practitioner. This flaw also can distort MU reporting since an incorrect date can shift a visit into the wrong MU reporting period.

143. One circumstance that caused EMA to assign an incorrect date to a visit involved provider notes stuck in finalizing status. This was a persistent bug in MMI's EHR. Thousands of provider notes became stuck in finalizing and did not become finalized until long after the note was created. This has many negative consequences for a practice.

144. First, it presents a danger to patient care since provider notes are not timely logged into the system. When the note is later finalized, through manual intervention, it reflects the date finalized or the date the note was created rather than the date the visit was completed. As such, encounters may be documented out of sequence and orders made during the encounters may be read in the wrong sequence, resulting in confusion and possibly incorrect prescription or treatment decisions.

145. Secondly, the problem distorts MU reporting since the delay in finalizing the note delays the date/time stamp of the note. Thus, events that occurred in one MU reporting period may be shifted to another reporting period. MMI management was aware of the implications for MU reporting. Adam Gresh (then Director of Software Engineering) acknowledged in an email on September 30, 2014: "One thing to keep in mind is that unfinalized visits are going to skew MU numbers and could be problematic."

146. MMI received many complaints from providers about this bug. For example, on October 8, 2014, an MMI Product Launch Manager wrote in an internal email: "The number of Ortho clients that have notes stuck in finalizing is increasing. They are emailing me regularly asking me when we are going to fix the problem [T]o the clients this is a critical issue without a practical work around. I have nothing to tell them other than we will get to it

eventually.” Another product manager responded on same day, “As we approach EMA Nation (a national users conference), this will be a hot topic of which we currently don’t have a response or solution. As well, this will kill NPS [Net Promoter Score, an indicator of customer satisfaction].”

147. This was a persistent problem across all versions of EMA. Despite repeated company assurances that the problem would be solved, it was not. As one example of a frustrated customer, a representative of DermOne, a large dermatology practice with offices in several states, wrote MMI on July 10, 2015:

Kindly refer to the email chain below as it relates to serious concerns over the integrity of visit notes stuck in “finalizing” status. My understanding is that this issue is not isolated to the NJ instance of EMA although just in this region alone, 339 records appear in this status.

When any of these visit notes are accessed, the time stamp changes to the current date and time. Catherine has several pdf examples for the same patient and same visit note showing that each time the note is accessed, the time and date stamp changes.

I am copying in Dan Cane and Dr. Sherling along with members of DermOne’s Executive and Compliance team as this issue must be made a priority for obvious legal and compliance reasons.

148. Another provider complained on August 16, 2015:

[P]ractice wide we have 7 notes stuck in “finalizing.” One of these is from May 5 [over three months earlier] . . . I don’t understand why this is still a problem for you guys – neither does your own tech support staff . . . Is this ever going to stop?”

149. At the time of Relator’s departure from MMI in July 2017, the problem of notes stuck in finalizing still existed and had not been comprehensively resolved.

150. A related bug that existed involved the software changing the date of a finalized note to the current date every time a user opened a patient’s finalized visit note. That flaw pulled visits forward months beyond the actual date of the visit.

151. A further problem that caused EMA to assign an incorrect time or date to a visit

was described in a company wiki page entitled “Passing, Storing and Searching Dates”:

In the course of troubleshooting MU reports we determined that there was an irrevocable loss of fidelity when we record only a date in the database. . . . This ends up automatically converting any date store in the database to midnight UTC on the date the database returns. This leads to a myriad of possible conversion scenarios and issue.

What this means is that in those instances where only a date but not an accompanying time is stored in the patient’s electronic record, EMA arbitrarily assigns a time of midnight UTC (Universal Time). When the EHR converts this time into the time zone of the location of the user, it can potentially assign the wrong date to the encounter. This can distort MU reporting since it can put a visit into a date that it should not and therefore incorrectly include (or exclude) visits from MU calculations.

8. MMI’s Software Failed to Handle Diagnostic Imaging and Laboratory Orders Reliably

152. To be certified as a Complete EHR under the 2011 and 2014 Edition certification criteria, a vendor’s software must provide computerized provider order entry, which requires users to be able to electronically order and record laboratory and radiology/imaging orders. This functionality must perform accurately, reliably, and safely to meet the certification requirement. In many circumstances, MMI’s software failed to meet this functionality.

153. Two recurring problems were: (1) lab results were not consistently placed in the patient’s record; and (2) many unmatched lab results sat in pending queues. An email exchange between MMI employees, forwarded to Relator on May 19, 2015, references an error rate of labs across the interface of 4%, indicating that 4% of lab orders sent out for results were not making it back into the correct patient’s record: “if we are erroring out 4% that will have a direct impact on lab revenues...”

9. MMI Failed to Satisfy Data Portability Requirements

154. To satisfy the 2014 Edition certification criteria, an EHR system must “[e]nable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient. . . .” 45 C.F.R. § 170.314(b)(7).

155. In addition to generating a set of export summaries, a certified EHR technology must permit batch export of these summaries in a single export action. On December 14, 2012, ONC published its “2014 Edition Test Procedure for §170.314(b)(7) Data Portability, Approved Test Procedure Version 1.2.” That guidance explained: “This test evaluates the ability for EHR technology to create a set of export summaries (according to Consolidated CDA format) for all patients (for example, a batch export) contained within the EHR technology”

156. On January 9, 2014, Drummond Group, acting in its capacity as an ATL, tested EMA version 3.0.0.12 on a limited number of certification criteria, one of which was the 314.b.7 requirement of batch exporting. Drummond reported that EMA failed the test, stating that MMI’s “EHR does not support the required capability of electronically creating a set of patient records (e.g. batch processing) but only allows creating individual patient records one-by-one.”

157. Relator is not aware of when or whether version 3.0.0.12 was retested on this criteria but based on comments of DGS about how MMI passed certification testing, Relator alleges on information and belief that MMI did not have this capability and, if it was retested, schemed upon retesting to show that it had this capability when in fact it did not.

158. Data portability was also a major problem for non-EMA to EMA conversions.

One aspect of data portability is migrating structured CCDA data from one EHR into another. MMI experienced considerable difficulty migrating structured CCDA data from a non-EMA EHR to EMA.

159. When converting data from a non-EMA EHR to EMA, MMI found that a great deal of information was placed in the “Other” category of the medical record rather than in the appropriate section of the record. This rendered the data migration so inefficient and difficult to use that it effectively meant that EMA could not, as a practical matter, satisfy data portability in those circumstances.

10. MMI Failed to Satisfy CCDA Requirements

160. “Consolidated clinical document architecture,” or CCDA, is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient’s healthcare, covering one or more healthcare encounters. Various MU Stage 2 criteria require an electronic summary of care document in conformance with established CCDA standards, including (i) 45 CFR § 170.314(b)(1) and (2), Transitions of care (when transitioning a patient to another care setting, the EP should provide a summary of care record); and (ii) 45 CFR § 170.314(e)(2), Clinical Summary (the EP should create clinical summaries for patient visits).

161. Based on internal MMI communications and Relator’s review of development tickets, Relator is informed and believes that EMA had numerous bugs preventing it from meeting CCDA standards.

11. Numerous Other Flaws In The EMA Software Render It Noncompliant With Certification Criteria

162. The failings of EMA discussed in this complaint are representative and are not meant to be exhaustive of all the flaws, defects, bugs, and problems that render EMA

noncompliant with certification criteria. MMI's bug lists, service tickets, development tickets, and complaint lists are replete with reports of problems related to virtually all the MU criteria, including those not mentioned above. Accordingly, Relator alleges on information and belief that MMI's software was unable to meet many ONC standards, implementation specifications, and certification criteria and was unable to perform in a reliable manner consistent with its certification.

E. MMI Knowingly Utilized an Incorrect Calculation Methodology for MU Measures that Caused its Customers to Submit False Information in MU Attestations to CMS

163. In order to qualify for Meaningful Use incentive payments, healthcare providers must not only use certified EHR technology, but must also attest to satisfying certain objectives and measures that correspond and relate to the certification criteria and standards.

164. MMI provided a software program to assist customers with MU attestation. Based on numerous reports of calculation errors for MU reporting, Relator is informed and believes that the calculation tool is inaccurate and unreliable, and, as a result, MMI caused users unknowingly to submit thousands of claims falsely attesting that they had qualified for federal incentive payments.

165. In an internal MMI spreadsheet entitled "Top Compliance Bugs from Clients and CS," current as of July 2017, MMI lists problems that range in severity from critical to low, as well as the path to resolution for these issues. Several of the issues that are listed as "not fixed" caused MU attestation numbers to be incorrect. For example:

- "EMA-72705 > MU/CQM Report: Not Calculating 90 days correctly > MU Report > High [Priority] > Not Fixed > Occurred w/ 2015 reporting. Not fixed. Should be fixed for 2016 reporting."

- “EMA-90101 > MU Objective 5 HIE: Outbound Referrals when removed should decrease denominator for this measure > MU Report > Critical [Priority] > In Progress [as of July 2017]”
- “EMA-7325 > Printed Status Overwriting ERx Status when ERx is printed after it’s eRxed. > MU Report > Critical [Priority] > Not fixed”
- “EMA-79535 > MU Report: Obj 2: Cannot pass with CDS/Drug and Allergy enabled MU Report > Critical [Priority] > Not fixed”

166. There were also recurrent problems with how EMA recorded the date and time of an event, which could distort MU reporting by shifting events from one reporting period into another. See ¶¶ 130-139 above.

167. Certifying body ICSA Labs notified MMI on November 18, 2015 that ONC had received a number of complaints concerning MMI’s EHR. Two of the complaints listed by ICSA related to flaws in the EHR’s MU calculation methodology that could result in inaccurate reporting:

ONC recently notified us of a batch of complaints concerning Modernizing Medicine’s EHR that were submitted through the ONC website. . . .

Summary of complaints -

- Inaccurate Clinical Quality Measure reporting – Providers do not have capability to document denominators or numerators for CQMs. Denominators and numerators completely different from PQRS measures.
- EHR not accurate in counting meaningful use data – only finalized visits are counted, yet EHR leaves most visits in non-finalized status. Modernizing Medicine refers to them as finalizing, but have indicated that visits do not count towards meaningful use.

168. In the same communication, ICSA notified MMI that in reviewing the recent complaints, ICSA discovered that MMI had not been submitting a complaint log to the certifying body, as required by federal regulations:

[I]n the course of investigating these complaints, we uncovered that there is some attestation information that is incomplete and required in order to maintain

your product certifications.

All certified HIT developers are required to log any complaints received about certified product functionality and send them to ICSA Labs for review. For CY2015 this was to be submitted at least annually, but going forward ONC will be requiring this on a quarterly basis beginning in the new year. **Within 10 business days, please send us a complaints log and associated actions taken for any complaints related to certified technology (specifically related to Meaningful Use functionality).** [Emphasis in original.]

169. Although Relator does not know whether MMI intentionally avoided submitting a Complaints Log to ICSA Labs until ICSA caught the omission, the omission conveniently allowed MMI not to reveal the magnitude and extent of customer complaints to the certifying body prior to that time.

170. Related to the flaws in how EMA performed MU calculations, MMI was also willing to change data on the back end (in the database itself) to help providers meet MU requirements. One way that MMI made changes on the back end was by “unfinalizing notes,” i.e., by going into the EHR system and making changes to notes that were already finalized. Relator strongly objected to this practice while employed at MMI but her concerns were ignored in the interest of keeping customers happy.

171. On August 3, 2016, an MMI employee prepared for his colleagues “a list of the most common scenarios where a Provider requests to ‘unfinalize’ a visit note.” One of the scenarios on the list was: “MU/PQRS changes (ex: didn’t perform med reconciliation before visit was marked final).” In other words, a common reason for providers to request MMI to unfinalize a note was to make changes to MU/PQRS reporting when the provider did not perform a required task in real time. By acceding to these requests on numerous occasions, MMI enabled its users to submit inaccurate attestation information in connection with their requests for federal incentive payments.

172. Another source of calculation errors occurred when MMI completed periodic development updates to its software logic, to correct calculation errors due to identified bugs and feature gaps. These updates are called “ANT targets.” An ANT target is effectively a series of scripts that run in the background of the application to complete specified tasks. When the ANT target is run, the software goes back through the time period specified and recalculates MU measures (and/or PQRs measures) using the new logic. DGC informed Relator that MMI regularly had errors in MU and PQRs calculations after running an ANT target.

F. MMI Knowingly Utilized an Incorrect Calculation Methodology for PQRs Measures that Caused its Customers to Submit False Information in PQRs Reports to CMS

173. In addition to causing providers to submit inaccurate MU calculations, EMA also caused providers to submit inaccurate PQRs reports. To qualify for upward Medicare payment adjustments or avoid downward payment adjustments under the PQRs program, providers must also attest to meeting the requisite number of PQRs measures.

174. Following is a sampling of recent customer complaints concerning PQRs reporting, taken from an MMI internal summary dated June 23, 2017:

Top PQRs Inquires/Complaints from the Past Couple Weeks
Complaints:

- “Due to the numerous instances of inaccurate PQRs data generated by EMA, we have lost confidence in Modernizing Medicine’s PQRs reporting services. We therefore had to submit via a third party Registry because we could not risk missing the deadline. While we understand that submission can be made via multiple options, we simply cannot trust the data that is being produced without verification and we do not currently have the resources to double check the results produced by EMA. We respectfully request that you issue a refund for the PQRs services we purchased.”
- “Why can’t this be fixed! If we miss the deadline there will be problems. We have done our part timely and there should be no reason it hasn’t been completed.”

....

- Why was data constantly erased and had to be reentered? . . .

175. The above complaints are representative of complaints across all versions of EMA.

176. In a press release in June 2017, MMI announced that as of March 31, 2017, it had submitted a total of 3,438 providers' 2016 PQRS data to CMS and that the majority were submitted via the company's PQRS qualified registry. According to the release, approximately 95 percent of the clients whose data were submitted using EMA met the PQRS minimum requirements. Because of flaws in EMA, Relator is informed and believes that MMI caused a number of these providers to submit false and inaccurate PQRS reports to CMS, resulting in unjustified upward payment adjustments and avoidance of downward payment adjustments.

177. Even when MMI corrected a flaw in the software's calculation of PQRS measures, MMI did so prospectively only, and did not go back and try to correct inaccurate reports already submitted. One example concerns services rendered pursuant to "incident-to" billing. "Incident-to" billing occurs when a physician extender (such as a Physician Assistant or Nurse Practitioner) sees the patient, but the visit is billed under the supervising physician.

178. During 2014, MMI's EHR treated a visit by an extender as counting towards the extender's PQRS reporting. MMI continued to do this in 2015; however, in December 2015, MMI came to the conclusion that this method of PQRS reporting was mistaken and that CMS regulations required extender visits to be included in the supervising physician's PQRS reports and not the extender's. On December 23, 2015 -- only a week before the end of the 2015 reporting period, and with no advance notice to providers -- MMI abruptly changed its method of calculating the incident-to measure, so that the supervising physician received credit for the visit.

179. Clients logging in on December 23, 2015 saw drastic changes to their PQRS

calculations because of the above change in methodology. In an internal MMI document entitled, “2015 FAQ Reporting Change,” MMI told its employees to downplay the change: “We are NOT calling this a bug fix.”

180. The change was disruptive and meant that many extenders could not meet the 2015 PQRS requirements. Of particular significance for present purposes, however, is that MMI only made the change in 2015 and did not go back and change the calculation for 2014, even though it had concluded that the previous method of PQRS reporting of incident-to services was in error.

181. In an internal “FAQ” for employees, MMI addressed how the employee should handle a provider who asks, “What about my 2014 reports?” The FAQ instructed employees to put the customer off in the following manner:

- What about my 2014 [PQRS] reports?
 - We are not bringing up 2014 reports. Only if the client asks about it. . . .
 - [Tell the customer:] “EMA is running an analysis on the 2014 data and will let you know if there is issues.”
 - If they are concerned, add their name to the list

182. Essentially this strategy was to look the other way and not go back and correct PQRS reporting errors in 2014 due to the incident to reporting error.

183. Some clients were furious that MMI had changed something so dramatic just days before the end of the year. When clients complained loudly enough, MMI agreed to change the numbers back to the old, mistaken way of calculating the PQRS report for extenders, in order to help them meet PQRS requirements. For example, an internal spreadsheet entitled, “2015 PQRS Clients who Want to Cancel_2014 Reviews,” lists customer complaints and MMI’s willingness to revert the calculation to the prior, incorrect method for the most vocal complainers:

Owensboro Dermatology (12/23/15)

From Maureen:

"I understand that you changed the PQRS report and why, but this must be changed back or fixed. Below are my concerns. . . .

. . . . This is completely unacceptable that you would change the report parameters so drastically at the end of the year. And we paid you for a service that you are now saying won't work for us. If you can't change the report, then i expect a refund for my three mid-level providers for PQRS reporting for 2015."

MMI Response

1/6/16: Jayne spoke with Maureen. They are going to write us an official [sic.] letter stating they want us to revert their PQRS back to EMA giving credit for primary provider as they were billing incorrectly. Once we get the letter, Ida will revert their data.

184. In sum, MMI was incorrectly calculating PQRS for incident-to services for 2014 and almost all of the 2015 period and had no intention of going back to 2014 and fixing the error. Additionally, when clients complained loudly enough, MMI was willing to revert their data to the incorrect calculation methodology to help them meet PQRS requirements.

185. Incorrect calculations of quality measures also would affect reimbursement under the MIPS program.

G. MMI Violated the Anti-Kickback Statute

186. MMI engaged in a range of conduct that violated the Anti-Kickback statute. Among other things, MMI employed an enhanced exclusive interface platform, an e-couponing program, a prescription prior authorization program, a consulting program, a referral program, a site visit program, and a reference program which violated the Anti-Kickback statute and caused the submission of false claims for payment to federal health care programs.

187. Through its enhanced exclusive interface platform, MMI intended to and did improperly influence providers using MMI's EHR to direct their lab orders to MMI's strategic partners, such as affiliated or allied companies or customer companies outside of MMI. These strategic partners would pay MMI for the benefit of these increased lab orders, including on a

per-lab-order fee basis.

188. Through its e-couponing program, MMI intended to and did improperly influence providers using MMI's EHR to prescribe certain drugs based on coupon recommendations provided by e-couponing companies. These e-couponing companies and MMI would obtain a financial benefit from the increased prescription of drugs for which the company promoted a corresponding coupon.

189. MMI's e-couponing program was designed for the purpose of inducing the purchase of certain drugs that therein financially benefitted MMI and the e-couponing companies with which MMI had relationships. Specifically, Director of Business Development crafted reports that would track on a weekly basis the financial returns from MMI's e-couponing programs and other similar programs. Other high-level MMI employees would consistently push to make sure that MMI's EHR was promoting and integrating coupons from these e-couponing programs.

190. Through its prescription prior authorization program, MMI intended to and did improperly influence providers using MMI's EHR to prescribe certain drugs based on prior authorization recommendations provided by prescription prior authorization companies. These companies and MMI would obtain a financial benefit from the increased prescription of drugs for which the company promoted a corresponding prior authorization.

191. Through its consulting program, MMI paid consultants and other leaders in specialized medical fields to refer and promote MMI and its EHR. MMI expended many thousands of dollars on these consultant programs and other similar business relationships to obtain improper referrals for MMI.

192. Through its referral program, MMI paid current users several hundred dollars for

each provider they referred who executed a contract with MMI. MMI tracked its referral program payments to determine if the referrals resulted in new business.

193. Through its site visit program, MMI paid current users to host prospective customers at their facility. The current user could receive an additional payment if the visiting practice purchased MMI's software.

194. Through its reference program, MMI paid current users to serve as references for prospective customers who wanted to speak with current users about the product. As with the site visit program, the current user could receive an additional payment if the prospective customer purchased MMI's software.

195. In addition, MMI also awarded very large credits to induce clients to continue using MMI's products despite their dissatisfaction with the products.

196. In addition, MMI manipulated the recommendations that would appear in its EHR. For example, MMI designed its EHR to improperly influence the prescribing decisions of providers so as to realize greater financial benefits for MMI. MMI likewise designed and codified its own protocols within its EHR instead of employing nationally recognized and standardized protocols. By using its own protocols, MMI sought to and did design protocols that would realize greater financial benefit for MMI.

197. The above conduct was willful, knowing and intentional, as well as reckless, and violates the Anti-Kickback statute and the False Claims Act. Requests to the Federal Government for incentive and other payments that resulted from unlawful kickbacks constituted false claims.

198. The above conduct violates the Anti-Kickback statute. Requests to the Federal Government for incentive payments that resulted from unlawful kickbacks

constituted false claims.

H. Modernizing Medicine Caused Submission of Upcoded Claims for Procedures and Services Reimbursed by Federal Health Insurance Programs

199. Modernizing Medicine competes with other electronic health records competitors by claiming that its software product – Electronic Medical Assistant or EMA – uses advanced technology and sophisticated algorithms to optimize patient care and revenues for providers.

200. In fact, providers do realize increased revenue because of purchase and implementation of EMA in their practices.

201. However, not all the increased revenue has been the result of increased efficiencies or correct billing.

202. Instead, providers using EMA have found that the software uses billing codes for both procedures and office visits that generate higher than appropriate billing revenue through upcoding of claims for reimbursement, including claims submitted to Medicare and other federal health programs.

203. Upcoding claims for reimbursement has taken several forms.

204. One cause of upcoding of reimbursement claims by EMA has been that the software misuses modifiers 25, 59, and 79 appended to procedures codes.

205. Modifier 25 is appropriately used to designate a significant and separately identifiable Evaluation and Management (E/M) service by the same physician or other provider on the same day of a procedure or other service. In other words, modifier 25, which generates additional revenue for an office visit, should only be used when the provider performs an exam which is significantly separate from any other service rendered that day.

206. Modifier 59 is appropriately used to indicate that a procedure or service performed was distinct and independent from other procedures or services performed on the same day on the same patient in the same facility by the same provider. Modifier 59 should not be appended to an E/M service and should not be used if there is another more specific and appropriate modifier to use. A distinct and separate procedure or service must be documented in the patient's medical records to substantiate use of modifier 59.

207. Modifier 79 is appropriately used to bill for an unrelated procedure or service by the same physician during the post-operative period. It is the appropriate modifier when a provider performs two unrelated procedures within the same day and/or when the second procedure is performed within the global period of the first procedure.

208. Mod Med received a series of reports and complaints from providers who identified that EMA was inappropriately using modifiers on claims they generated for reimbursement. Some providers notified Mod Med that they were concerned that an audit of reimbursed claims would discover the misused modifiers and recoup money from the provider.

209. These problems with incorrect modifiers persisted over time. For example, in March 2013, Danielle Zarnowiec and Dr. Shearling identified that EMA was adding modifier 25 to CPT codes for radiographic interpretation and ultrasounds.

210. Nonetheless, in June 2015, incorrect usage of modifier 25 was identified again in a ticket recorded as MED-8932. Providers reported similar concerns with use of modifier 59 which was being appended to procedure codes without regard to whether procedures were documented as unrelated (MED-16590). Mod Med even recognized that modifiers would be removed from automatically appearing with a particular procedure

code only to reappear later MED-6809 and MED-15442). Modifier misuse was identified by Mod Med and its customers even with very common procedures such as treatment for meniscus tears or joint injections frequently billed by orthopedic practices.

211. On information and belief based on personal knowledge and reasonable investigation, Mod Med caused submission of claims with improperly used modifiers to federal programs.

212. Mod Med also caused the submission of upcoded claims for E/M services from 99213 to 99214 through a treatment algorithm which upcoded the service based upon use of criteria that should not have justified a 99214 E/M claim. This issue of upcoding E/M codes from 99213 to 99214 was known by Mod Med starting at least by June 2014 and was still an ongoing issue when Relator left Mod Med in 2017. Mod Med managers and employees recognized that the E/M code would be upcoded to 99214 even without required elements but simply if the patient's status was updated within the record. (MED-13971).

213. In May 2017, Rick Trefzger, Vice President of Sales, recorded reports from providers about E/M upcoding and noted that one provider had told him they had "reported for over a year, for a majority of the encounters has to manually override the bill because it is over coding. Examples included claims where no history or physical exam was documented and the software was still billing an office visit as a 99214." The provider noted to Trefzger that this was a "ongoing and very frequent issue" and that "they do not feel comfortable that our documentation codes the appropriate level and that they were at risk of an audit" with EMA. The same provider also noted that they had been reporting the incorrect use of modifiers to increase reimbursement within the system for

over a year.

214. Senior managers including Dr. Shearling were aware of the upcoding of E/M claims and that it put providers at risk of audit recoupment for submitting false claims but made a business decision that the increased reimbursement was a selling point for EMA with many providers. No major modifications were made to correct the upcoding errors on the assumption that any billing problems would be attributed to providers as they could override claims.

215. Upcoded claims are material to payment and are false claims. Mod Med acted with actual knowledge, deliberate indifference and recklessness in providing software that caused providers to submit claims for reimbursement to federal programs and other insurers seeking reimbursement for more than was appropriate for the actual office visit, service provided or procedure performed

VI. CLAIMS FOR RELIEF

216. MMI obtained its EHR certifications through a series of false statements and fraudulent conduct. MMI's EHR system did not -- and could not -- meet both the certification criteria and the incentive payment requirements in its operation in the field, and MMI concealed the failure from its certification bodies and the Government. MMI caused Eligible Professionals falsely to attest to using certified EHR technology and to satisfying Meaningful Use objectives and measures and to submit false information on their attestations requesting incentive payments.

217. MMI also knowingly caused customers who participated in the Medicare program to submit false and inaccurate data on PQRS quality measures to CMS and to the MIPS program, which resulted in the customers receiving upward payment adjustments, or

avoiding downward payment adjustments, to which they were not entitled.

218. In addition, MMI's violations of the Anti-Kickback statute and knowing upcoding of claims submitted to federal health insurance programs for services and procedures, caused providers to submit false claims for payment to the Government.

219. Through the conduct discussed above, MMI knowingly caused the submission of false claims and false statements material to false claims to be submitted to the Government.

Count One
False Claims Act
31 U.S.C. §§ 3729(a)(1)(A), (B), (C), & (G)

220. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 220 above as though fully set forth herein.

221. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

222. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

223. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment by the Government.

224. By virtue of the acts described above, Defendants knowingly caused its customers to conceal or improperly avoid or decrease an obligation to pay or transmit money or property to the Government;

225. By virtue of the acts described above, Defendants knowingly conspired with

others to violate the FCA. Moreover, Defendant took substantial steps toward the completion of the goals of that conspiracy by the conduct alleged herein.

226. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants; conduct. The false claims were presented by several separate entities. Relator does not have access to the records of all such false or fraudulent statements, records or claims.

227. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

228. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

229. Additionally, the United States is entitled to the maximum penalty for each and every violation arising from Defendants' unlawful conduct alleged herein.

PRAYER

WHEREFORE, *qui tam* Plaintiff-Relator Amanda B. Long prays for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.*
2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty for each violation of 31 U.S.C. § 3729;
3. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act.

4. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

5. That Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: May 25, 2021

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